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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,907	09/25/2003	Gisele Veilleux	GOUD:037US	6020

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

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01/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/670,907	VEILLEUX ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *11 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 5 require that both pyridoxine HCL and Doxylamine Succinate be provided but it is unclear in the subsequent steps that the final product will contain both the pyridoxine and doxylamine as step (b) permits an embodiment in which only one of the above is mixed with an excipient and it is not clear in step (e) that the "at least one other active ingredient" must include the pyridoxine or doxylamine which was not selected in step (b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9,11,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (US Pat. 5,260,069) in view of Chu et al. (US Pat. 6,419,954), Bishai et al.. and the acknowledge prior art.

Chen discloses a process of for preparation of pulsatile particles which can contain combinations of therapeutic agents in which the granule containing the active agents and swelling agent are prepared by the well known and economic roller compaction method with sieving to select granules of particular mesh size (Column 1, lines 56-68, Column 2, lines 60-65). It is disclosed that the particles can be contained in capsules or compressed into tablets with a binding agent which can dissolve promptly in any aqueous medium or be in the form of an enteric tablet to resist dissolution until after passing through the stomach (Column 5, lines 16-31).

Chu et al. disclose embodiements in which a tablet can further include untreated active agents (e.g. without coating material or in powders) in addition to the active agent-containing particles and that the active agent particles can contain vitamins or drugs, such as in which the active agent can be vitamins or drugs, such as, doxylamine succinate (Column 9, lines 59-68, Column 10, lines 15, 16). It discloses that any suitable method for granulation can be used including roll compaction (Column 12, lines 25-44).

Bishai et al. disclose that the combination of 10mg doxylamine succinate and 10 mg pyridoxine HCl is safe and effective in treating nausea and vomiting associated with pregnancy (NVP)(Pages 167, 170,173-177).

The Applicant acknowledges that doxylamine succinate and pyridoxine HCL are obtained in the form of powders having different granular sizes which makes it very difficult to

uniformly mix them in dry state long with require excipients (Paragraph 0003). It is acknowledged that the loss of pyridoxine HCL during processing is due to the small size of and possible electrostatic charge of the Pyrdoxine HCL particles and that simply account of the loss by using increased amounts of Pyridoxine HCl does not result in consistant results (Paragraph 0004).

The prior art discloses preparation of granules containing active ingredients and excipients by the well known method of roller compaction and sieving to obtain appropriate mesh size granules which are used for form pulsatile particles which are compressed into enteric coated tablets or enclosed in capsules. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of more than one active ingredient, such as the combination of doxylamine succinate and pyridoxine HCl. However, the prior art amply suggests the same as the prior art discloses that the granules can include combinations of therapeutic agents, such as vitamins and doxylamine succinate, the prior art discloses the combination of doxylamine succinate and pyridoxine HCl and that pyridoxine HCL and doxylamine succinate are provided in different granular sizes. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of doxylamine succinate and pyridoxine in granules prepared by roller compaction and sieving to obtain appropriate mesh size would be safe and effective in treating NVP.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Actions and the further reasons below.

Contrary to the Applicant's arguments, it is acknowledged by Applicant that pyridoxine HCl and doxylamine succinate are in the form of powders having different granular sizes and that said lack of uniformity creates problems in processing in terms of loss of pyridoxine HCl. Since the prior art discloses that processes using compaction rollers in which the size of the particles can be selected, it would have been well within the skill of and one of ordinary skill in the art to select a particle size which was sufficiently large enough to avoid loss during processing. The examples set forth in the Specification do not appear to show unexpected activity. One of ordinary skill in the art would not expect the pyridoxine HCl particles to adhere to the roller in any significant amount as upon compaction the pyridoxine HCl will no longer consist of individual small particles.

Even if the example showed unexpected data, the same is not commensurate in scope with the claims. The method tested was limited to mixing pyridoxine HCL and Doxylamine Succinate with excipients, compacting, breaking and sieving to obtain a specific mesh size 16.. As the size of the particles is a well known factor in the loss of the active ingredient due to adherence to processing equipment and the use of more processing equipment or repeated steps in a given processing equipment increases the opportunities of loss due to adherence, the testing of a single mesh size and the use of a finite number of steps (i.e. limiting the opportunity for adherence to processing equipment) is not commensurate in scope with the claims which are not limited to any specific mean granule size or any specified mesh size or time of contact with processing equipment of particles that are of a size that would tend to adhere to said equipment. See In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at "elevated temperatures" using a certain ion

exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term "elevated temperatures" encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also In re Peterson, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium).

The Examiner has reviewed the Canadian prosecution documents provided by the Applicant. However, since the determination of allowability of claims of a US Patent Application based on the opinion of a foreign country would be contrary to the requirement that examination be governed by the relevant US statutes, rules, decisions, opinions, etc., the rejection is maintained notwithstanding the decision of the Canadian Patent Office with respect to the claims in the related Canadian application. See e.g. MPEP, Introduction, Forward.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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